REPORT OF A PILOT STUDY ON THE INSERTION OF A LIPPES LOOP EARLY IN THE PUERPERIUM FOR CONTRACEPTION*

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Interest in intra-uterine contraceptive devices was renewed in 1959 by Oppenheimer[2] of Israel when he reviewed his experience with Grafenberg rings. At the same time Ishihama[1] of Japan reported on intra-uterine devices in 19,567 women.

Since then different devices have been scientifically tested in various countries and the effectiveness of intra-uterine devices has been established in controlling conception. With the advent of polyethylene and stainless steel devices the dangers of infection and irritation of the uterus reported with the earlier Grafenberg rings have practically disappeared.

In spite of the popularity of contraceptive pills there is a definite place for intra-uterine devices, mainly for 3 reasons.

1. They are much cheaper and therefore more acceptable for mass contraception.

2. There is no need for meticulous counting, and women of the lowest social class can therefore successfully control their fertility with their aid.

3. Some women have to discontinue the pill because of side-effects and in them the intra-uterine device may be a suitable substitute.

The idea of an intra-uterine device for contraception is of course as old as the hills. For many centuries Arabic and Turkish camel owners have used intra-uterine contraception to prevent pregnancy in their pack animals. A small round stone, the size of an apricot seed, is inserted into the uterus through a hollow tube.[3] In 1930 Grafenberg had already reported on the use of a silver intra-uterine ring in 600 patients with a 1·6% pregnancy rate. The

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devices in common usage today are:

The Hall stainless steel ring, the Ota plastic ring, the Zipper nylon ring, the Birnberg Bow, the Margulies Spiral and the Lippes Loop.

As I am going to report on a series using the large Lippes Loop I have extracted the latest available figures for the Lippes Loop from the fourth progress report from the Population Council's Cooperative Statistical Study (National Council of Maternal Health) in the USA (Table I).

TABLE I. NCMH — POPULATION COUNCIL 1964; LIPPES LOOP (LARGE)

Number of insertions	4,770
Months of use	27,772
Number of pregnancies	33
1·3 per hundred woman-years exposure	
First expulsion rate	9%
Removal rate	
Medical	11·8%
Personal	2·3%
Cumulative rate of continuing use = 77·4%.	

In 4,770 insertions with 27,772 months of use there were 33 reported pregnancies with a rate of 1·3 per 100 woman-years exposure. In the 33 pregnancies the device was *in situ* in 17 and position undetermined in 16 when the pregnancy was diagnosed.

The first expulsion rate was 9·0 per 100 cases; 26·6% of these were unnoticed by the patient. With re-insertions 37·4% were re-expelled.

Removal of the device for medical reasons occurred in 11·8% and removal for personal reasons occurred in 2·3% of cases.

The cumulative rate of continuing use, which is a rough measure of long-term effectiveness and acceptability, was 77·4%.

MOTIVATION FOR EARLY PUERPERAL INSERTION

It is generally advised and accepted that intra-uterine devices should not be inserted sooner than 4 - 6 weeks following delivery. The pilot study reported here was instituted primarily to find out whether the Lippes Loop could not be inserted successfully in the first week after delivery while the patient is still in the hospital.

At the Karl Bremer Hospital we treat both White and non-White patients. Although the White patients attend the postnatal clinics fairly regularly we find that the non-White patients ignore our appeals to return for a postnatal examination where contraceptive advice can be given. Many of the non-White patients desire contraceptive advice, but take no active steps to visit designated clinics and consequently find themselves delivering babies more or less annually and contrary to their desires. An additional problem at the Karl Bremer Hospital is that we admit a high percentage of obstetrically and medically complicated non-White patients of whom a large percentage need urgent contraceptive advice for medical reasons. The advantages of a contraceptive device which could be inserted in the puerperium while the patient is still in hospital is therefore quite obvious for this class of patient.

While I was visiting the United States of America recently, Dr. Anne Southam, of the Department of Obstetrics and Gynaecology, College of Physicians and Surgeons, Columbia University, New York, mentioned that at a recent conference on intra-uterine devices the possibility had been mentioned of inserting intra-uterine devices in the puerperium. She supplied me with 100 Lippes Loops of the large size and I decided to conduct a pilot study on the feasibility of introducing the loop during the puerperium.

We inserted the loops in both Whites and non-Whites. In the non-White patients who remain in hospital for a very short time following vaginal delivery the loops were inserted from the 1st to the 4th day following delivery, while in the White patients the loop was inserted from the 5th to the 8th day following delivery.

The Insertion

The insertion was done in the bed with the patient either on her back with her knees drawn up or in the left lateral position. After bimanual examination to exclude pelvic abnormalities and to note the size and position of the uterus, the patency of the cervix was also noted. At 3 - 5 days following birth the cervix still easily admits two fingers. A bivalve speculum was used to expose the cervix. The patients experienced no pain on insertion of the loop and there was no marked increase of lochia following the insertion. The loop must, however, not be inserted too high into the cavity else the polyethylene threads will not extrude through the cervix.

The only contraindications were recent delivery by caesarean section and puerperal infection.

Follow-up

Since many of these patients live in very unhygienic conditions, routine long-acting sulphonamides were given by mouth prophylactically for 3 weeks following insertion.

The first follow-up examination was done within 14 days of insertion and the second follow-up 2 months later or following the first menstruation, whichever occurred the soonest. The first insertions were done in March 1965 and we are reporting on the last insertions done till 15 May 1965, with the follow-up till 16 June 1965.

The patients were given a sheet explaining what had been done, and they were asked to keep a look-out for the passage of the loop, abnormal bleeding or pain and to report back sooner if these occurred.

Experience

Although the advantages of early puerperal insertion were envisaged mainly for the non-White patients, we found that we could not evaluate the method in them because they defaulted in their follow-up visits. The evaluation is therefore dependent mainly on our experience in the White patients.

TABLE II. PUERPERAL INSERTIONS

Whites	44
Non-Whites	29
Total	73
Postabortal Insertions	
Whites	1
Non-Whites	5
Total	6

Our experience to date relates to 73 insertions following full-term delivery (44 Whites and 29 non-Whites) (Table II). We have also inserted a loop in 6 cases following evacuation for incomplete abortion. The figures for Whites and non-Whites are tabled separately, because the time of insertion in the two groups differs, apart from the fact that the follow-up in the non-Whites was very unsatisfactory.

In all patients a Papanicolaou smear was taken at each visit. All the patients showed class I or II smears, and there were none with class III, IV or V smears in this series.

Whites—Puerperal Insertions

Up till 15 May 1965 44 loops were inserted. Two patients were lost to follow-up and 27 were available for 2 months' follow-up, of whom 20 had already menstruated.

Expulsions

The crux of this experiment was really to see whether the loops would be expelled or not. We were surprised and delighted to find that in spite of the patency of the cervix at the time of insertion there was a relatively low expulsion rate in the Whites. In the 27 patients who had reported for the 2 months' follow-up there were 3 expulsions and 1 case where the position of the loop was found to be unsatisfactory. In the 42 cases available for 1 month follow-up there was 1 additional case where the position of the loop was found to be unsatisfactory (Table III).

TABLE III. EXPULSION RATE — WHITES

27 Patients, insertion 2+ months before	
Expulsions	3
Unsatisfactory position	1
42 Patients, insertion 1+ month before	
Expulsions	3
Unsatisfactory position	2

With regard to the 27 cases with 2 months follow-up, Table IV shows the incidence of expulsions in relation to the parity of the patient. Table V shows the incidence of expulsions in relation to the time of insertion of the loop.

TABLE IV. INCIDENCE OF EXPULSIONS IN RELATION TO PARITY OF 27 WHITES AT 2 MONTHS FOLLOW-UP

	Parity					
	1	*2*	*3*	*4*	*5*	*6*
Number of insertions	4	6	11	1	3	2
Expulsions	—	2	1	—	—	—
Unsatisfactory position	—	1	—	—	—	—

TABLE V. INCIDENCE OF EXPULSIONS IN RELATION TO TIME OF INSERTION IN 27 WHITES AT 2 MONTHS FOLLOW-UP

	Day of insertion							
	4	*5*	*6*	*7*	*8*	*12*	*14*	*16*
Number of insertions	1	6	10	3	3	1	2	1
Expulsions	—	—	2	—	—	1	—	—
Unsatisfactory position	—	—	1	—	—	—	—	—

Note

At least 20 of the patients had already menstruated when they reported for follow-up and in only 1 patient was there an expulsion during menstruation.

SHORT RESUMÉ OF THE PATIENTS IN WHOM THE LOOP WAS EXPELLED

Case 1. Mrs. V.R. 24 years old. Para 2 + 0.

The loop was inserted on the 6th day (5.3.65). She did not come for her first follow-up within 14 days after insertion. She had her first menstruation on 15 May and the loop was expelled on the next day. The loop was re-inserted on 18 May. She menstruated again on 16.6.65. Following this menstruation the loop was still in a satisfactory position.

Case 2. Mrs. V.Z. 36 years old. Para 3 + 0.

Loop inserted on the 6th day. At the first routine follow-up 9 days later no threads were visible through the cervix. The patient was not aware of having passed the loop. X-ray examination confirmed that the loop had been passed. A loop was re-inserted on 20.4.65 and found to be satisfactory on 4.5.65. To date the patient has not reported back.

Case 3. Mrs. L. 22 years old. Para 2 + 0.

Loop inserted on the 12th day postpartum. The loop was expelled 2 days later. A similar loop was re-inserted on the same day and 6 weeks later at follow-up it was still in a satisfactory position.

REPORT ON TWO PATIENTS IN WHOM THE LOOP WAS IN AN UNSATISFACTORY POSITION

Case 4. Mrs. M. 23 years old. Para 2 + 0.

Insertion on the 6th day postpartum. At the routine follow-up 12 days later the lower end of the loop was visible in the endocervix. The loop was removed and another one re-inserted. 14 days later, on 13.4.65, the position was found to be satisfactory. During the second menstruation following the insertion the loop was expelled and the patient refused to have further insertions.

Case 5. Mrs. B. 21 years old. Para 1 + 0.

Loop inserted on the 8th day of the puerperium and found to be satisfactory one week later. However, when seen on 15.6.65, 30 days after the insertion, the point of the loop could be felt high up in the cervix. This was pushed back into the uterine cavity and the patient was observed further. Subsequently the loop was removed and another inserted which was satisfactory.

SIDE-EFFECTS IN 27 PATIENTS FOLLOWED UP FOR 2 MONTHS OR LONGER

1. *Pain.* Apart from slight cramps for the first 12 - 24 hours following insertion, there were no patients complaining of severe pain. 23 patients positively stated that they had no pain. 3 patients complained of a slight pain in the iliac fossae and 1 patient complained of dyspareunia, but none of them wished to have the device removed on account of the pain.

2. *B'eeding.* This was difficult to assess in view of the normal occurrence of lochia and the marked individual variation among patients as regards amount of lochia and duration of lochial discharge. Only 1 patient complained of continuous vaginal bleeding for 2 months. On examination no abnormality could be found. This patient also refused to have the device removed on account of the complaint. 20 patients had experienced their first menstruation; 12 stated that menstruation had been quite normal, 4 that the flow had been slightly increased and 4 that the flow had been excessive.

3. *Infection.* One patient developed a temperature of 103°F with pain in the hypogastrium and tenderness in both iliac fossae. The loop was removed. It was subsequently found, however, that the cause of the temperature was a urinary infection. This was the only patient in whom the loop was removed for medical or personal reasons.

Experience in non-White Patients

The follow-up of the non-White patients has been extremely unsatisfactory and we have not been able to trace patients even through home visits. Of 29 patients available for one month follow-up we can report on only 16, and of 15 patients available for 2 months follow-up we can report on only 1.

In the 16 patients followed up for one month there were 4 expulsions on the 1st, 2nd, 5th and 16th days following insertion respectively.

Table VI shows the relation of the expulsions relative to the day of insertion.

TABLE VI. NON-WHITES, 29 INSERTIONS; 16 FOLLOW-UPS FOR UP TO ONE MONTH

Day 1.	Insertions 5,	expulsions 2
Day 2.	Insertions 6,	expulsions 1
Day 3.	Insertions 1,	expulsions 0
Day 4.	Insertions 4,	expulsions 1

(Actual incidence of expulsions of 4 per 29 insertions)

In this small series there is a higher incidence of expulsions in the non-Whites. This may be related to the parity. The average parity of the non-Whites was 8·2 compared to 3·0 in the Whites. However, it is more likely to be related to the earlier insertion of the loop in the non-Whites. In the latter the loop was inserted within the first 4 days following delivery whereas in the Whites the loop was inserted later, i.e. mostly on the 5th and 6th day following delivery. Larger numbers are necessary to confirm these impressions. In the non-White series there were no removals of the loop for medical or personal reasons.

Postabortal

In 6 selected cases of abortions we have inserted the loop one day after evacuation. There were no untoward symptoms, no expulsions, and 2 patients have since menstruated without expelling the loop.

SUMMARY

1. A pilot study of intra-uterine insertion of the large Lippes Loop in 73 patients in the first week following vaginal delivery has been presented.
2. In 27 White patients followed up for 2 months or longer the loop was expelled in 3 and the position was unsatisfactory in a fourth. Re-insertion of the loop was successful in these cases.
3. In no patient was it necessary to remove the loop on account of bleeding or pain.
4. With prophylactic long-acting sulphonamide therapy there was no incidence of genital infection.
5. In one patient the loop was removed on account of a urinary infection.
6. This method merits further extensive trials, especially in those patients who need contraceptive advice, but fail to visit contraceptive clinics soon enough following the birth of their last baby.

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